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*\*Pro hac vice* Petition to be filed

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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA  
LAS VEGAS DIVISION**

MICHELLE PRZYBOCKI;  
KETAN VAKIL; and  
GOURMEND FOODS, LLC,

Plaintiffs,

vs.

UNITED STATES DEPARTMENT OF  
AGRICULTURE;  
THOMAS J. VILSACK, in his official capacity  
as Secretary of Agriculture;  
UNITED STATES DEPARTMENT OF  
AGRICULTURE FOOD SAFETY AND  
INSPECTION SERVICE;

Civil Action No. 2:23-CV- 00455

**COMPLAINT FOR DECLARATORY  
AND INJUNCTIVE RELIEF**

1 SANDRA ESKIN, in her official capacity as  
2 United States Deputy Under Secretary for Food  
3 Safety;  
4 UNITED STATES FOOD AND DRUG  
5 ADMINISTRATION; and  
6 ROBERT CALIFF, in his official capacity as  
7 Commissioner of the United States Food and  
8 Drug Administration,  
9  
10 Defendants.

11 Plaintiffs Michelle Przybocki, Ketan Vakil, and Gourmend Foods, LLC file this  
12 Complaint for Declaratory and Injunctive Relief and sue the United States Department of  
13 Agriculture (the “USDA”); Thomas J. Vilsack, in his official capacity as United States Secretary  
14 of Agriculture; the United States Department of Agriculture Food Safety and Inspection Service  
15 (“FSIS”); Sandra Eskin, in her official capacity as United States Deputy Under Secretary for Food  
16 Safety; the United States Food and Drug Administration (the “FDA”); and Robert Califf, in his  
17 official capacity as Commissioner of the United States Food and Drug Administration, as follows:

## 18 INTRODUCTION

19 1. This is a First Amendment challenge on behalf of Michelle Przybocki, a consumer  
20 desiring factual information about the ingredients in foods, and Ketan Vikal, who, through his  
21 small business Gourmend Foods, LLC (“Gourmend”), wants to convey this same factual  
22 information to Michelle and others like her. That information is about difficult-to-digest sugars  
23 known as FODMAPs (an acronym for fermentable oligosaccharides, disaccharides,  
24 monosaccharides and polyols). Gourmend’s food products are factually, verifiably low-  
25 FODMAP, and Ketan and Gourmend want to convey this truthful information on the Gourmend  
26 labels. Michelle, who is extremely sensitive to FODMAPs, wants to see these facts on  
27 Gourmend’s and many other businesses’ food labels so that she can improve her quality of life  
28

1 by more easily identifying the foods that will not upset her digestion and aggravate her medical  
2 condition.

3         2. But the federal government categorically bans this truthful speech. Worse, this ban  
4 (the “Ban”) is not because of any contention that the information is inaccurate, false, or  
5 misleading in any way—Gourmend’s products are verifiably low-FODMAP, and the Agencies  
6 have not claimed otherwise. Rather, the USDA, FSIS, and the FDA (collectively, the “Agencies”)  
7 Ban the use of the words “low-FODMAP” and related factual statements on food labels simply  
8 because they are not on the Agencies’ outdated list of pre-approved nutrient content information  
9 that can be provided on food labels. Moreover, even attempting to change the federal regulations  
10 to add new information to the preapproved list takes years and far more resources than most  
11 people possess.

12         3. This lawsuit seeks to vindicate the First Amendment free speech rights of Ketan  
13 and Gourmend to tell the truth on food labels and Michelle’s First Amendment right to receive  
14 that truthful information that businesses like Gourmend would voluntarily choose to provide but  
15 for the Ban. Put simply, the First Amendment does not allow the government to decide which  
16 facts consumers are allowed to learn.

#### 20 THE PARTIES

21         4. Plaintiff Michelle Przybocki (pronounced Prizz-bahki) is a citizen and resident of  
22 this district and was residing in this district during all the events at issue in this lawsuit.

23         5. Plaintiff Ketan Vakil (pronounced Vah-keel) is a citizen and resident of New York  
24 City, New York. Through his business, Gourmend Foods, LLC, Ketan does business in this  
25 district.  
26  
27  
28

1           6.       Gourmend Foods, LLC (“Gourmend”) is a New York limited liability company in  
2 good standing and doing business in this district.

3           7.       Ketan is Gourmend’s managing member and sole member.  
4

5           8.       Defendant the United States Department of Agriculture (the “USDA”) is a federal  
6 agency charged with regulating food labeling and enforcing regulations on food labels, among  
7 other things.

8           9.       Defendant Thomas J. Vilsack is the United States Secretary of Agriculture.  
9 Secretary Vilsack has direct authority over the United States Department of Agriculture’s  
10 personnel and is charged with the responsibility of enforcing the related laws, regulations, and  
11 policies of the United States. He is being sued only in his official capacity.  
12

13          10.       Defendant the United States Department of Agriculture Food Safety and  
14 Inspection Service (“FSIS”) is a federal agency that is part of the United States Department of  
15 Agriculture and is charged with regulating food labeling.  
16

17          11.       Defendant Sandra Eskin is the United States Deputy Under Secretary for Food  
18 Safety. Deputy Under Secretary Eskin has direct authority over the United States Department of  
19 Agriculture Food Safety and Inspection Service’s personnel and is charged with the responsibility  
20 of enforcing the related laws, regulations, and policies of the United States. She is being sued  
21 only in her official capacity.  
22

23          12.       Defendant the United States Food and Drug Administration (the “FDA”) is a  
24 federal agency charged with regulating food labeling. It is part of the United States Department  
25 of Health and Human Services.

26          13.       Defendant Robert Califf is Commissioner of the United States Food and Drug  
27 Administration. Commissioner Califf has direct authority over the United States Food and Drug  
28

Administration's personnel and is charged with the responsibility of enforcing the related laws, regulations, and policies of the United States. He is being sued only in his official capacity.

### JURISDICTION AND VENUE

14. Plaintiffs bring this civil rights lawsuit pursuant to the United States Constitution and the Declaratory Judgment Act (28 U.S.C. § 2201) for violations of the First Amendment to the United States Constitution.

15. Plaintiffs seek a declaration that the Ban on the use of "Low FODMAP" and related truthful statements on food labels violates the First Amendment, as well as both temporary injunctive relief and permanent injunctive relief against enforcement of the Ban.

16. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 (federal question jurisdiction) and 1343(a)(3) (civil rights jurisdiction).

17. Venue lies in this Court pursuant to 28 U.S.C. § 1391(b)(2) and (c)(1). Lead Plaintiff Michelle Przybocki resides in this District and has done so since 1976. As a result, most of the witnesses for this case are located in this district. Additionally, Plaintiffs Ketan Vakil and Gourmend Foods, LLC, do business in this district, and the Defendants all operate in this district as well.

### FACTUAL ALLEGATIONS

***A. Michelle Przybocki needs to be able to easily identify low-FODMAP foods.***

18. Plaintiff Michelle Przybocki is a speech therapist living and working in Las Vegas, Nevada.

19. In 2019, Michelle became very ill and nearly died of digestive complications. After that, whenever Michelle ate, she would often experience debilitating pain.

1           20.     Michelle learned that she had a severe case of irritable bowel syndrome (“IBS”)  
2 and that if she wanted to reduce the pain to a manageable level, she should follow a low-FODMAP  
3 diet.

4           21.     “FODMAP” is an acronym that stands for “fermentable oligosaccharides,  
5 disaccharides, monosaccharides, and polyols.”  
6

7           22.     FODMAPs are certain carbohydrates, or sugars, that can cause intestinal distress.

8           23.     FODMAPs can be found in certain foods and ingredients that are commonly used  
9 to impart flavor, such as onions and garlic.  
10

11          24.     FODMAPs are well-known in the mainstream scientific and medical communities.

12          25.     IBS is a digestive disorder that affects 10-15% of the American population. The  
13 population of the United States is over 330 million people. That means 33 to 50 million Americans  
14 potentially suffer from IBS.

15          26.     IBS is not the only digestive disorder that impacts the lives of a substantial number  
16 of Americans.  
17

18          27.     Michelle’s IBS symptoms made daily living a struggle. Often, after Michelle ate,  
19 she would suffer from extreme pain that would immobilize her for many hours.

20          28.     Michelle’s symptoms kept her confined to her home for extended periods of time.

21          29.     Michelle’s experience is not unique.  
22

23          30.     A low-FODMAP diet is commonly recommended by doctors to people who suffer  
24 from IBS and other intestinal issues.

25          31.     Studies have shown that most patients report significant improvement of their IBS  
26 symptoms when they eliminate FODMAPs from their diet.  
27  
28

1           32. For many people, following a low-FODMAP diet is the key to avoiding pain and  
2 to living a normal life.

3           33. For these reasons, Michelle decided to follow a low-FODMAP diet.

4           34. Michelle needed to find low-FODMAP foods to have any chance of living a  
5 somewhat-normal life.  
6

7           35. Michelle spent countless hours searching for low-FODMAP foods, only to  
8 discover that prepared and packaged foods almost never provided this information.

9           36. Because this information was not provided on food labels, it was extremely  
10 difficult for Michelle to find food products that were certain to be low-FODMAP.  
11

12           37. This meant that Michelle would typically spend several hours each time she went  
13 to the grocery store scouring food label ingredient lists in the desperate hope of identifying high-  
14 FODMAP foods, so she could avoid them.

15           38. But even careful review of an ingredient list typically will not reveal whether a  
16 food is high or low in FODMAPs.  
17

18           39. This is because different parts of the same type of ingredient can be high-  
19 FODMAP or low-FODMAP.

20           40. For example, one part of a green onion will be low-FODMAP, while the rest of  
21 the green onion is high-FODMAP, so an ingredient list that includes “green onions” will be of no  
22 help to someone who is searching for low-FODMAP foods.  
23

24           41. When a food product’s ingredient list features an ingredient that could potentially  
25 be low-FODMAP, that food product might nonetheless still be high-FODMAP.

26           42. Conversely, when a food product’s ingredient list features an ingredient that could  
27 potentially be high-FODMAP, that food product might nevertheless still be low-FODMAP.  
28

1           43.     This made it extremely difficult for Michelle to find packaged foods indicating  
2 whether the foods were low-FODMAP.

3           44.     In the first few months in which Michelle attempted to stop eating high-FODMAP  
4 foods, she barely ate because she could not find enough low-FODMAP foods, and she  
5 consequently suffered an unhealthy amount of significant weight loss.  
6

7           45.     Eventually, Michelle was able to piece together a low-FODMAP diet for herself,  
8 but the lack of low-FODMAP labeling continues to negatively impact her quality of life.

9           46.     Michelle desperately needs to know which prepared and packaged foods are low-  
10 FODMAP.  
11

12           47.     Michelle's quality of life would be substantially improved if food labels were  
13 allowed to indicate whether the foods were low-FODMAP.

14           48.     Upon information and belief, and given the prevalence of IBS and other digestive  
15 disorders in the United States, many food businesses would make more low-FODMAP foods if  
16 they were allowed to tell consumers on their food labels that the low-FODMAP foods were indeed  
17 low-FODMAP.  
18

19           49.     Michelle knows of at least one food producer that would provide this truthful,  
20 factual low-FODMAP information on its food labels if the Ban were not prohibiting the food  
21 producer from communicating that information.  
22

23           ***B.     Plaintiffs Ketan Vakil and Gourmend want customers to know that their foods  
24 are low-FODMAP.***

25           50.     Ketan Vakil is an entrepreneur who lives in New York, New York. Ketan has a  
26 master's degree in business administration from New York University.

27           51.     Like Michelle, Ketan suffers from a digestive disorder.  
28



1           52. Like Michelle, Ketan has decided to follow a low-FODMAP diet to avoid  
2 digestive pain.

3           53. Like Michelle, when Ketan tried to find packaged foods with labels indicating that  
4 they are low-FODMAP, he found it to be nearly impossible and highly frustrating.  
5

6           54. Ketan loves good food. He developed a few recipes for low-FODMAP broths and  
7 spice blends that helped impart great flavor into his low-FODMAP diet so he could continue to  
8 enjoy eating.

9           55. Eventually, it occurred to Ketan that others like him with sensitive stomachs might  
10 appreciate his low-FODMAP recipes.  
11

12           56. Ketan saw—and experienced for himself—an unmet need in the marketplace:  
13 foods that could be trusted to be low-FODMAP.

14           57. Not realizing that the lack of options in the marketplace had been caused by the  
15 federal government's Ban, Ketan decided to start a business dedicated to producing low-  
16 FODMAP foods.  
17

18           58. In 2018, Ketan founded Gourmend to do just that.

19           59. Gourmend is a food business that develops, markets, and sells food products that  
20 are low-FODMAP.

21           60. Ketan is the sole employee of Gourmend.  
22

23           61. Gourmend works with co-manufacturers and co-packers to manufacture and  
24 package Gourmend's products to Gourmend's specifications.

25           62. Gourmend currently sells its food products to consumers throughout the United  
26 States.  
27  
28

1           63.     The majority of Gourmend's sales are over the internet, but some of Gourmend's  
2 sales are also through retail stores.

3           64.     Ketan has sought and obtained, and intends to continue seeking and obtaining,  
4 third party verification of the fact that Gourmend's products are low-FODMAP.  
5

6           65.     All of Gourmend's food products have been verified as low-FODMAP by Monash  
7 University.

8           66.     Monash University is a research university. It is Australia's largest university and  
9 is considered to be one of the world's leading universities.  
10

11           67.     Monash University is recognized as the world leader in the area of low-FODMAP  
12 foods and diet.

13           68.     Monash University lab-tests food products to measure their FODMAP content.

14           69.     If a food is low-FODMAP according to Monash's standards, it is considered  
15 Monash University Low FODMAP Certified.  
16

17           70.     If a food product is certified low-FODMAP by Monash University, Monash  
18 University permits the food manufacturer to include the Monash University Low FODMAP  
19 Certified stamp of approval and trademarks on product packaging, promotional materials,  
20 websites, social media, in-store advertising, and more.

21           71.     Monash University has lab-tested each of Gourmend's food products.  
22

23           72.     Each of Gourmend's food products are certified low-FODMAP by Monash  
24 University. Gourmend has the right to use the Monash University Low FODMAP Certified stamp  
25 of approval and trademarks.

26           73.     By the summer of 2022, Gourmend was selling five products. These consisted of  
27 four low-FODMAP spice blends and one low-FODMAP chicken broth.  
28

74. Ketan included the Monash University Low FODMAP Certified stamp of approval and/or trademarks on each Gourmend product label.

75. Also included on all Gourmend labels at the time were other true, non-misleading, statements regarding Gourmend's low-FODMAP foods. These provided information to consumers that the products: (i) were low-FODMAP; (ii) were for the amount of one serving low in FODMAPs; and (iii) were Monash low-FODMAP certified.

76. Gourmend has since added additional related information to its labels informing consumers that the food products are "deliciously digestible" and "gut loving."

77. For example, the following is a true and correct image of Gourmend's current chicken broth labels with the low-FODMAP information:



1           78. In the summer of 2022, Ketan was ready to expand the Gourmend product line to  
2 include low-FODMAP beef broth.

3           79. Gourmend attempted to include on its initial low-FODMAP beef broth label the  
4 same low-FODMAP information that is included on its low-FODMAP chicken broth label.  
5

6           80. Ketan and Gourmend intend to sell additional low-FODMAP products with this  
7 labeling information, but the Ban has delayed them from doing so.

8           ***C. The USDA and FDA have jurisdiction over different food products, but***  
9           ***low-FODMAP information is banned from food labels regardless.***

10          81. The labels on Gourmend's products are regulated by the USDA, FSIS, and the  
11 FDA.

12          82. Specifically, the USDA (and therefore FSIS) has jurisdiction over the label for  
13 Gourmend's low-FODMAP beef broth, while the FDA has jurisdiction over Gourmend's low-  
14 FODMAP chicken broth and spice blend labels.  
15

16          83. The USDA has jurisdiction over products containing meat, including beef broth.  
17 21 U.S.C. §§ 601 *et seq.* (the Federal Meat Inspection Act ("FMIA")). Specifically, § 607 of the  
18 FMIA empowers the USDA to regulate food labels.  
19

20          84. The Food Safety and Inspection Service ("FSIS"), an agency within the USDA,  
21 has been delegated the primary responsibility of regulating meat products under the FMIA,  
22 including the regulation of labels. 7 C.F.R. § 2.18(a)(1)(ii)(B) and § 2.53(a)(2)(ii).

23          85. The FDA has jurisdiction over food labeling for foods under its purview pursuant  
24 to 21 U.S.C. §§ 301 *et seq.* (the Federal Food, Drug, and Cosmetic Act ("FFDCA")) and 15 U.S.C.  
25 §§ 1451 *et seq.* (the Fair Packaging and Labeling Act ("FPLA")).  
26  
27  
28

1           86.     21 U.S.C § 607(d) provides that “no article subject to [the FMIA] shall be sold . . .  
2 under any name or other marking or labeling which is false or misleading . . . but established trade  
3 names and other marking and labeling and containers which are not false or misleading and which  
4 are approved by the Secretary are permitted.”

5  
6           87.     21 U.S.C § 607(e) provides that “[i]f the Secretary has reason to believe that any  
7 marking or labeling . . . in use or proposed for use with respect to any article subject to [the FMIA  
8 / the PPIA] is false or misleading in any particular, he may direct that such use be withheld unless  
9 the marking, labeling, or container is modified in such manner as he may prescribe so that it will  
10 not be false or misleading.”

11  
12           88.     21 U.S.C § 601(n)(1) and 21 U.S.C. § 343(a) provide that a food is “misbranded,”  
13 and therefore violates the FMIA or FFDCA, if the food’s label “is false or misleading in any  
14 particular.”

15           89.     21 U.S.C. § 343(a) states, similar to the FMIA, that a food product is misbranded  
16 if “its labeling is false or misleading in any particular[.]”

17  
18           90.     The FMIA and FFCDA both define “label,” in relevant part, as “a display of  
19 written, printed, or graphic matter upon the immediate container (not including package liners)  
20 of any article.” 21 U.S.C. § 601(o) and § 321(k).

21           91.     The FMIA and FFCDA both define “labeling” as “all labels and other written,  
22 printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2)  
23 accompanying such article.” 21 U.S.C. § 601(p) and 21 U.S.C. § 321(m).

24  
25           92.     This definition of “labeling” is broad, making the regulations applicable not only  
26 to product labels, but also to materials that accompany the product. For instance, the definition  
27 can encompass point-of purchase materials.  
28

1           93. Congress has directed the USDA and the FDA to consult and cooperate as to  
2 labeling standards to avoid inconsistency. 21 U.S.C. § 607(c); 15 U.S.C. § 1455(c). As a result,  
3 the USDA's and the FDA's food labeling regulations largely mirror each other, and regulators at  
4 the Agencies can, and regularly do, consult with one another regarding food labeling.  
5

6           94. The relevant federal regulations include 9 C.F.R. § 317.313, which states when  
7 nutrient content claims are allowed.

8           95. The result is that "implied" or "undefined" nutrient content claims are not allowed  
9 on food labels (the "Ban").  
10

11           96. For the purposes of determining whether a nutrient content claim is Banned for  
12 being "implied" or "undefined," "defined" means defined in the federal regulations.

13           97. For example, the nutrient content claim "low-fat" is defined in the federal  
14 regulations and can therefore be used on food labels if the use is consistent with the federal  
15 regulations.  
16

17           98. Any nutrient content claims that are not defined in the federal regulations are  
18 Banned from being used on food labels.

19           99. Any nutrient content claims that are merely implied are Banned from being used  
20 on food labels.  
21

22           100. Because low-FODMAP statements are not defined in the federal regulations, they  
23 are considered either "undefined" or "implied" and are therefore Banned.

24           ***D. The USDA and FSIS require sellers to obtain preapproval before using food***  
25           ***labels, while the FDA does not, but all three Agencies are causing speech to be***  
26           ***chilled.***

27           101. The USDA, through FSIS, has promulgated rules regulating the content and design  
28 of meat product labels. 9 C.F.R. §§ 317.1 *et seq.*

1           102. The FDA has promulgated rules regulating the content and design of food labels.  
2 21 C.F.R. §§ 101.1 *et seq.*

3           103. Even though USDA and FDA food labeling standards and regulations mirror each  
4 other, the USDA and the FDA enforce those standards and regulations differently.  
5

6           104. The relevant USDA enabling statute, the FMIA, provides that “established trade  
7 names and other marking and labeling and containers which are not false or misleading and which  
8 are approved by the Secretary are permitted.” 21 U.S.C § 607(d).

9           105. The USDA interprets these provisions as mandating that USDA must preapprove  
10 food labels before those foods can be offered for sale. Therefore, before a food seller is legally  
11 permitted to offer a food product for sale, it must get its label pre-approved by the USDA (through  
12 FSIS).  
13

14           106. The relevant FDA enabling statutes do not have a similar provision. They simply  
15 provide that misbranded labels are prohibited and that the Secretary has the authority to  
16 promulgate regulations “for the efficient enforcement of [the statute].” 21 U.S.C. 331(a); 21  
17 U.S.C. 371(a).  
18

19           107. The FDA has not adopted the USDA’s label pre-approval requirement. Instead,  
20 the FDA monitors compliance through surveillance of products already on the market and  
21 enforces its regulations by sending “warning letters” to food manufacturers.  
22

23           108. 21 U.S.C § 610(c) (FMIA) and 21 U.S.C. § 331 (FFDCA) prohibit the introduction  
24 of misbranded food into interstate commerce.

25           109. Pursuant to 21 U.S.C. § 676(a) and 21 U.S.C. § 333(a), each violation can result  
26 in imprisonment of up to one year, a fine of up to \$1,000, or both.  
27  
28

1           110. FSIS may also prohibit the shipment or sale of product (21 U.S.C. § 672; 9 C.F.R.  
2 § 500.2)), refuse to allow the marks of inspection to be applied to products (21 U.S.C. § 671; 9  
3 C.F.R. § 500.3)), and initiate seizure and condemnation proceedings (21 U.S.C. § 673).

4           111. The fact that the USDA and FSIS require food label preapproval for the types of  
5 foods under the USDA's and FSIS's jurisdiction means that, because of the Ban, the USDA and  
6 FSIS prevent low-FODMAP information from being provided on those food labels.

7           112. If a food seller attempts to obtain label preapproval from the USDA or FSIS for a  
8 label that includes low-FODMAP information, the USDA and FSIS will refuse to approve the  
9 label until such time as the low-FODMAP information is approved.

10           113. Upon information and belief, the USDA and FSIS are aware that the low-  
11 FODMAP information is truthful, verifiable, factual information that could help tens of millions  
12 of Americans.

13           114. The USDA and FSIS enforce the Ban anyway.

14           115. The FDA does not require food label preapproval for the foods under its  
15 jurisdiction.

16           116. The FDA enforces the Ban.

17           117. The FDA's most-common manner of enforcing the Ban is by sending letters (often  
18 referred to as "warning letters" or "dear manufacturer letters") instructing the food sellers that  
19 they are violating the Ban and must stop providing information on their labels informing  
20 consumers that the food products are low-FODMAP.

21           118. In addition to sending "warning letters" and "dear manufacturer letters," the threat  
22 of FDA enforcement caused by the fact that Ban exists chills speech.



1           119. Neither the FDA, the USDA, nor FSIS has ever publicly stated that the Ban will  
2 not be enforced.

3           120. Neither the FDA, the USDA, nor FSIS has ever publicly stated that the food sellers  
4 do not need to comply with the Ban.  
5

6           121. Upon information and belief, the FDA is aware that the low-FODMAP  
7 information is truthful, verifiable, factual information that could help tens of millions of  
8 Americans.

9           122. The FDA enforces the Ban anyway.  
10

11           ***E. Gourmend applied for low-FODMAP label approval and was denied.***

12           123. In July 2022, Gourmend, through its co-packer, submitted its low-FODMAP beef  
13 broth label to FSIS for preapproval.

14           124. That is when Ketan learned that his truthful labels were illegal.

15           125. Prior to July 2022, Gourmend had not had any complaints or legal problems.  
16 Indeed, other than the events discussed in this Complaint, Gourmend has still experienced no  
17 other complaints or legal problems.  
18

19           126. For Gourmend's low-FODMAP beef broth, Ketan included the same truthful,  
20 factual, low-FODMAP statements that are included on all Gourmend's other labels.

21           127. Gourmend's beef broth is factually, verifiably low-FODMAP, and the statements  
22 on its label about the fact that it is low-FODMAP were neither false nor misleading.  
23

24           128. But when Gourmend, through its co-packer, submitted the label for pre-approval,  
25 FSIS demanded Ketan "remove all references to digestible, gut loving, and fodmap."  
26  
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1           129. The USDA expressly instructed Gourmend that Gourmend’s low-FODMAP beef  
2 broth label could not receive the necessary preapproval unless it removed all references to being  
3 low-FODMAP or easy to digest.  
4

5           130. The USDA expressly instructed Gourmend that no versions of these statements  
6 could be made because these entire categories of statements were banned from being included on  
7 food labels as a result of the Ban.

8           131. The USDA expressly instructed Gourmend that nothing could be done to fix these  
9 statements other than to remove them because these entire categories of statements were banned  
10 from being included on food labels as a result of the Ban.  
11

12           132. When Gourmend expressed its dissatisfaction with the USDA’s and FSIS’s  
13 official position, the FSIS Deputy Director of Labeling and Program Delivery, Jeffrey Canavan,  
14 instructed Gourmend on September 20, 2022, that USDA and FSIS staff had discussed  
15 Gourmend’s labels with their colleagues at the FDA and that the FDA agreed with the USDA’s  
16 and FSIS’s position that these types of statements were categorically banned.  
17

18           133. Deputy Director Canavan explained to Gourmend that the Agencies consider the  
19 term “Low FODMAP” and any related factual statements to be undefined nutrient content claims.  
20

21           134. FSIS defines a nutrient content claim as “[a] claim, which, expressly or by  
22 implication, characterizes the level of a nutrient . . . of the type required in nutrition labeling[.]”  
23 9 C.F.R. § 317.313(b).

24           135. Similarly, the FDA defines a nutrient content claim as a claim “that expressly or  
25 implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling[.]”  
26 21 C.F.R. § 101.13(b).  
27  
28

1           136. An “expressed nutrient content claim” is any direct statement about the level of a  
2 nutrient in the product,” with one example being “low sodium.” 9 C.F.R. § 317.313(b)(1); 21  
3 C.F.R. § 101.13(b)(1).

4           137. FSIS and the FDA prohibit the use of any nutrient content claims that are not  
5 specifically defined in the regulations. 9 C.F.R. § 317.313(b); 21 C.F.R. § 101.13(b). *See also*  
6 FSIS guidance document *A Guide to Federal Food Labeling Requirements for Meat, Poultry, and*  
7 *Egg Products*, at 73, and FDA guidance document *Guidance for Industry: Food Labeling Guide*,  
8 at 72.

9           138. Deputy Director Canavan informed Gourmend that “FSIS regulations define ‘low’  
10 and ‘high’ for various nutrients but do not define ‘low FODMAP.’” Furthermore,  
11 “oligosaccharides, disaccharides, and monosaccharides [the O, D and M in “FODMAP”] are a  
12 subset of carbohydrates, and FSIS does not have nutrient content claims for carbohydrates.”

13           139. In other words, the USDA, FSIS, and the FDA enforce a pre-approved and  
14 exclusive list of the statements that can be made about nutrient contents in food. This list is in the  
15 federal regulations, and if a nutrient content claim does not appear on this list, then it cannot be  
16 lawfully used on a food label.

17           140. Deputy Director Canavan explained that Gourmend’s factual claims about  
18 FODMAPs are not on that list and that it is therefore illegal for Gourmend to make those claims.

19           141. At no point has the USDA, FSIS, the FDA, or anyone else ever claimed that  
20 Gourmend’s low-FODMAP statements were false or misleading.

21           142. As explained by Deputy Director Canavan, the entire reason Gourmend could not  
22 tell consumers on its food labels that its low-FODMAP products were low-FODMAP was that  
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1 this information was prohibited by the Ban because this information does not appear in the  
2 regulations' list of preapproved nutrient content claims.

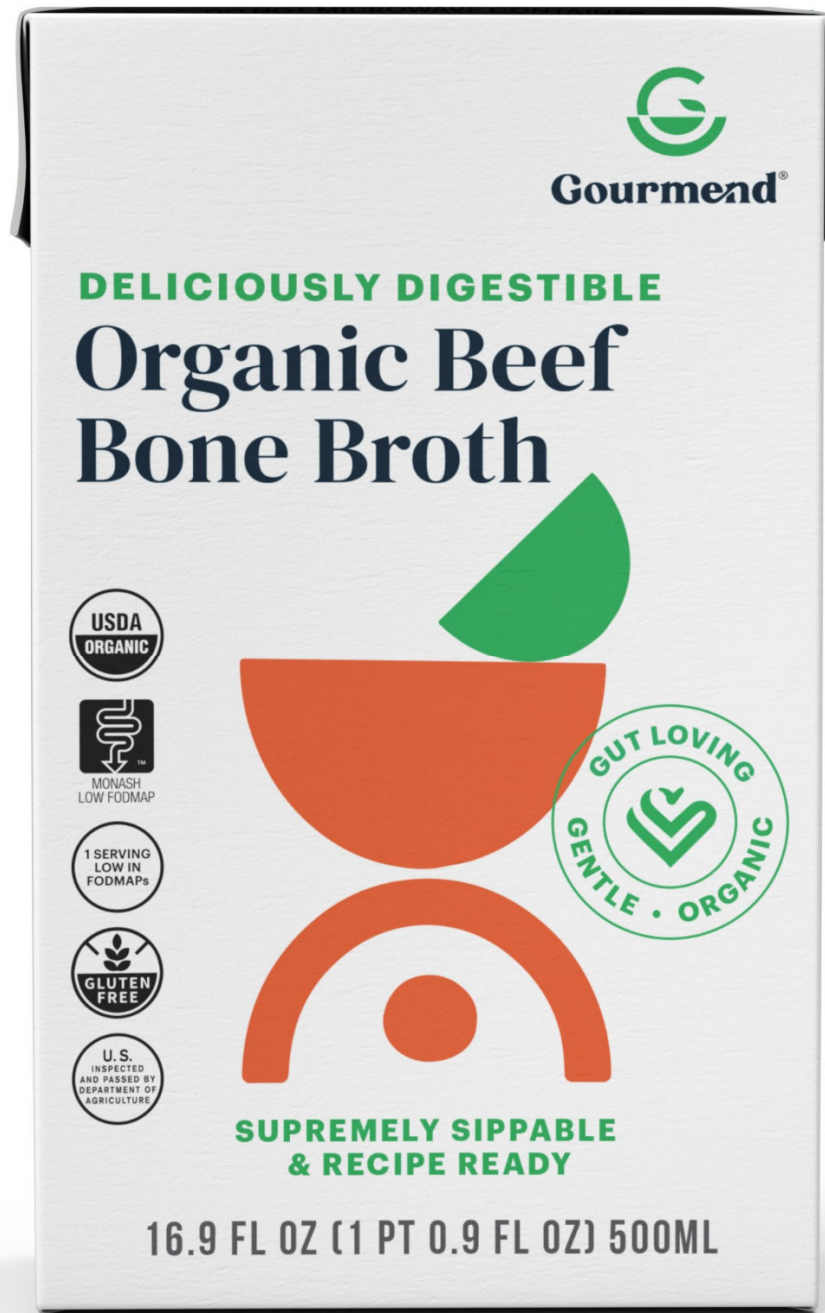
3 143. Deputy Director Canavan was correct that the truthful statements that Gourmend  
4 would like to make on its labels about its foods being low-FODMAP are not on the Agencies'  
5 preapproved list and are therefore prohibited by the federal regulations' Ban.  
6

7 144. As a result, Gourmend did not appeal the USDA's determination. Instead,  
8 Gourmend was forced to amend its application to remove the low-FODMAP statements from its  
9 beef broth label, after which the USDA approved the label.  
10

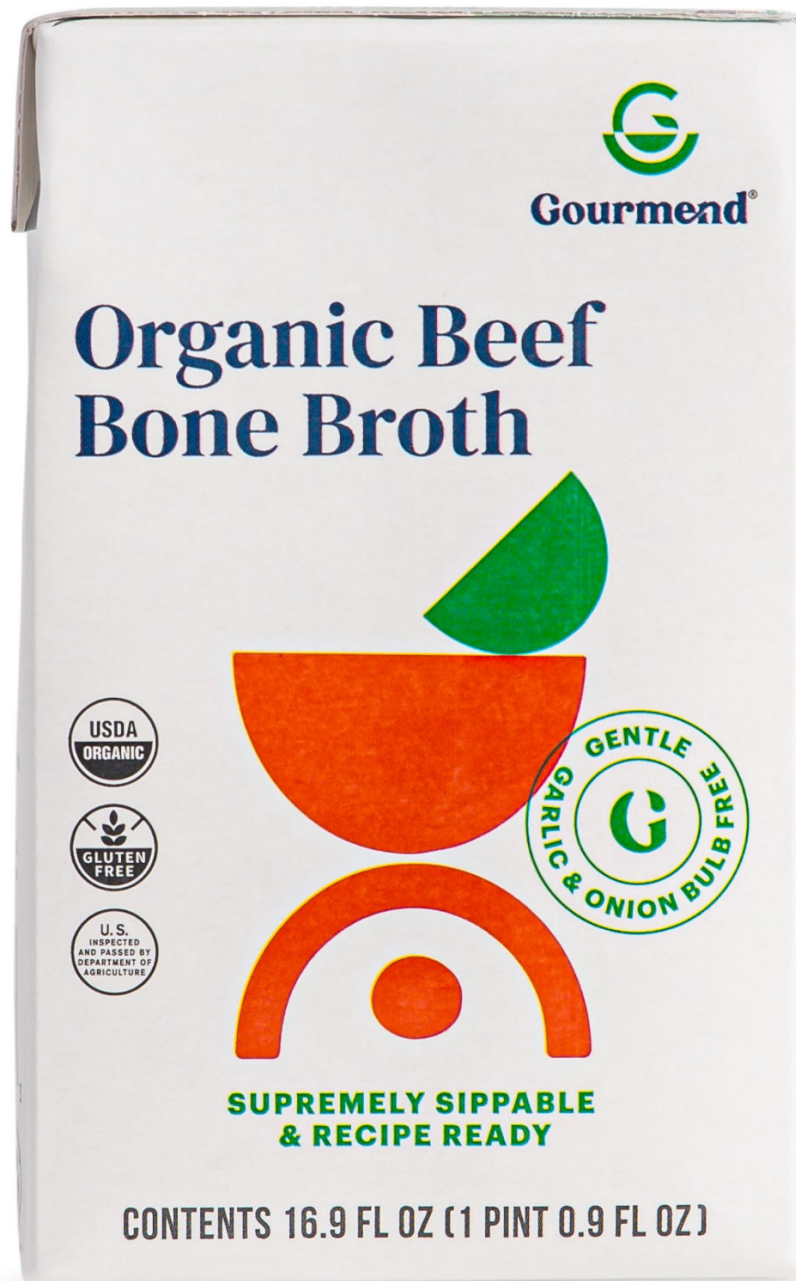
11 145. Gourmend is currently selling its low-FODMAP beef broth, but because of the  
12 Ban, the label cannot inform consumers that it is low-FODMAP.

13 146. If Gourmend were to reapply, this truthful, factual information would again be  
14 rejected by the USDA because the regulations continue to ban this information.

15 147. The following is a true and correct image of the beef broth label with low-  
16 FODMAP information that Gourmend would be using today but for the Ban:  
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148. The following is a true and correct copy of the beef-broth label without the low-FODMAP information that Gourmend is currently forced to use because of the Ban:



149. The Ban is unconstitutional.

150. If Plaintiffs were to prevail in this lawsuit, Gourmend would reapply for preapproval of its preferred beef broth label with the low-FODMAP information, and the label would be approved by the UDSA.





1           160. Because of the Ban, Ketan is considering removing the low-FODMAP information  
2 from the labels for Gourmend's chicken broth and spice blends.

3           161. The Agencies enforce the Ban.

4           162. The Ban and the Agencies' enforcement of the Ban are chilling Ketan's speech.

5           163. In addition to Gourmend's beef broth label, the Ban has further chilled Ketan and  
6 Gourmend's speech by causing them to delay plans for additional speech and additional low-  
7 FODMAP food products.

8           164. Upon information and belief, but for the Ban, other businesses would be providing  
9 more low-FODMAP information on their food labels to consumers.

10           165. Upon information and belief, the presence of factual and non-misleading  
11 statements on food products that low-FODMAP food products are indeed low-FODMAP would  
12 improve the quality of life of millions of Americans.

13           166. The Agencies' Ban on the factual, non-misleading claim "Low FODMAP" and  
14 related factual, non-misleading claims about foods being low-FODMAP does not protect  
15 consumers but instead harms them.

16           167. The Agencies' censorship of low-FODMAP information on food labels directly  
17 results in consumers being kept ignorant of or confused about the content of the foods they  
18 purchase.

19           168. Selling Gourmend products without complying with the Ban could result in  
20 substantial fines for Gourmend and numerous other problems, including possible forced closure  
21 of the business.

22           169. Selling Gourmend products without complying with the Ban could result in  
23 incarceration of up to one year per offense for Ketan.



1           170. Selling Gourmend products without complying with the Ban could result in the  
2 seizure and condemnation of Gourmend products being shipped across state lines.

3           171. Low-FODMAP foods, including Gourmend's products, are legal to sell across  
4 state lines, provided that labeling requirements are met.

5           172. Other than the labeling requirements challenged here, Gourmend has met all  
6 USDA and FDA requirements for the sale across state lines of its beef broth, chicken broth and  
7 spice blends.  
8

9           173. But for the Ban, Michelle would currently be receiving factual, non-misleading  
10 information on each Gourmend product package that the product is low-FODMAP.

11           174. But for the Ban, Gourmend would be selling its beef broth with an honest, accurate,  
12 non-misleading label providing useful information to consumers that its beef broth is low-  
13 FODMAP. Instead, it is forced to exclude this truthful, verifiable, factual information from its  
14 beef broth label.  
15

16           175. But for the Ban, Gourmend would be truthfully labeling its beef broth as low-  
17 FODMAP and providing related, truthful statements about the fact that its beef broth is low-  
18 FODMAP.  
19

20           176. If Gourmend were allowed to provide low-FODMAP information on its low-  
21 FODMAP beef broth, then it would do so.

22           177. Because its customers prefer low-FODMAP foods, Gourmend is suffering  
23 ongoing and irreparable harm each day it is not allowed to sell its low-FODMAP beef broth with  
24 an honest, non-misleading label describing its low-FODMAP beef broth as low-FODMAP.  
25  
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1 178. Michelle, Gourmend’s customers, and the general public have been harmed by  
2 Gourmend’s inability to lawfully offer low-FODMAP beef broth with an honest, non-misleading  
3 label discussing the fact that it is low-FODMAP due to the Ban.  
4

5 179. USDA, FSIS, and FDA procedures are inadequate to prevent this ongoing  
6 irreparable injury.

7 180. Any additional efforts to contact the USDA, FSIS, or the FDA to attempt to resolve  
8 these issues would be futile.

9 181. The USDA, FSIS, and the FDA do not have the power to grant the relief Plaintiffs  
10 seek without an order from this Court.  
11

12 182. Plaintiffs are not required to attempt to change federal regulations before bringing  
13 a First Amendment challenge to those same federal regulations.

14 **FIRST CAUSE OF ACTION: MICHELLE’S RIGHT TO FIRST AMENDMENT**  
15 **FREEDOM OF SPEECH AS A RECIPIENT OF INFORMATION**

16 183. Plaintiffs incorporate and re-allege the allegation contained in paragraphs 1  
17 through 182 of this Complaint as if fully set forth herein.

18 184. This cause of action is brought under the First Amendment of the United States  
19 Constitution, which provides that “Congress shall make no law . . . abridging the freedom of  
20 speech.”  
21

22 185. The Free Speech Clause of the First Amendment protects the right of individuals,  
23 entrepreneurs, and businesses and to express themselves—including through food labels. It also  
24 protects the right of consumers to read or hear that speech that businesses would voluntarily  
25 choose to provide, so that the consumers can consider it in making their purchasing decisions.  
26  
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1           186. Indeed, one of the most-important cases in modern commercial speech  
2 jurisprudence was a case brought by consumers who challenged a restriction on price advertising  
3 and prevailed at the United States Supreme Court. *See Va. State Bd. of Pharm. v. Va. Citizens*  
4 *Consumer Council, Inc.*, 425 U.S. 748 (1976).

5  
6           187. Labeling low-FODMAP foods as being low FODMAP is truthful, verifiable, non-  
7 misleading speech about lawful activity.

8           188. Labeling low-FODMAP foods with information about how the foods are low  
9 FODMAP is truthful, verifiable, non-misleading speech about lawful activity.

10  
11           189. All the information that Michelle seeks is truthful, verifiable, non-misleading  
12 speech about lawful activity.

13           190. But for the Ban, more businesses would provide this information on their labels.

14           191. The businesses that would provide more low-FODMAP information on their food  
15 labels but for the Ban include Gourmend.

16  
17           192. Upon information and belief, many additional businesses would provide more  
18 low-FODMAP information on their food labels but for the Ban.

19           193. If more businesses provided low-FODMAP information on their food labels,  
20 Michelle would use this information while making purchasing decisions.

21           194. If more businesses provided low-FODMAP information on their food labels, it  
22 would materially improve Michelle's quality of life.

23  
24           195. By banning the honest, accurate, non-misleading description of low-FODMAP  
25 foods, the Ban has violated Michelle's First Amendment rights.

1           196. The Ban irreparably harms Michelle by denying her access to truthful information  
2 that food sellers would voluntarily choose to provide about lawful goods in the marketplace but  
3 for the Ban.

4           197. The irreparable harm that the Ban is causing to Michelle is ongoing.

5           198. The Ban also irreparably harms other consumers by denying them access to  
6 truthful information that food sellers would voluntarily choose to provide about lawful goods in  
7 the marketplace but for the Ban, and this irreparable harm is ongoing.  
8

9           199. The Ban is a content-based restriction on speech.

10           200. Banning the use of certain terms like “Low FODMAP” is inherently content based.

11           201. Banning statements related to the fact that a food is low FODMAP is inherently  
12 content based.  
13

14           202. Moreover, even if the Ban were not content based, it would still violate the First  
15 Amendment’s guarantee of freedom of speech.

16           203. The Ban results in the suppression of truthful speech about the sale of lawful  
17 products.  
18

19           204. The Ban results in Michelle and other consumers not getting highly valuable  
20 information that can have a significant impact on their quality of life.

21           205. The Ban does not satisfy any level of First Amendment scrutiny.

22           206. The Ban does not further any legitimate governmental interests at all and only  
23 harms the public.  
24

25           207. The Ban facially violates Michelle’s right to free speech guaranteed by the First  
26 Amendment to the United States Constitution.  
27

1           208. As applied to Michelle, the Ban violates her right to free speech guaranteed by the  
2 First Amendment to the United States Constitution.

3           209. Unless Defendants are enjoined from enforcing the Ban, Michelle will continue to  
4 suffer ongoing irreparable harm.  
5

6           **SECOND CAUSE OF ACTION: KETAN’S AND GOURMEND’S RIGHT TO FIRST**  
7           **AMENDMENT FREEDOM OF SPEECH**

8           210. Plaintiffs incorporate and re-allege the allegation contained in paragraphs 1  
9 through 182 of this Complaint as if fully set forth herein.

10           211. This cause of action is brought under the First Amendment of the United States  
11 Constitution, which provides that “Congress shall make no law . . . abridging the freedom of  
12 speech.”  
13

14           212. The Free Speech Clause of the First Amendment protects the right of individuals,  
15 entrepreneurs, and businesses to express themselves—including through food labels. It also  
16 protects the right of consumers to read or hear that speech and consider it in making their  
17 purchasing decisions.

18           213. Labeling low-FODMAP foods as being low FODMAP is truthful, verifiable, non-  
19 misleading speech about lawful activity.  
20

21           214. All the information that Gourmend would like to provide on its food labels consists  
22 of truthful, verifiable, non-misleading speech about lawful activity. This includes (i) “low  
23 FODMAP”; (ii) “1 serving low in FODMAP”; (iii) “low FODMAP certified”; (iv) “deliciously  
24 digestible”; and (v) “gut loving.”  
25

26           215. By banning the honest, accurate, non-misleading description of low-FODMAP  
27 foods, the Ban has abridged the freedom of speech of Ketan Vakil and Gourmend Foods, LLC,  
28

1 and of anyone who would otherwise sell perfectly safe, low-FODMAP food products with an  
2 honest, accurate, non-misleading label.

3 216. The Ban irreparably harms Gourmend by preventing it from engaging in truthful  
4 speech about lawful goods that it wants to sell.

5  
6 217. The Ban also irreparably harms consumers by denying them access to truthful  
7 information that food sellers would voluntarily choose to provide about lawful goods in the  
8 marketplace but for the Ban.

9 218. The Ban is a content-based restriction on speech.

10 219. Banning the use of certain terms like “Low FODMAP” is inherently content based.

11 220. Moreover, even if the Ban were not content based, it would still violate the First  
12 Amendment’s guarantee of freedom of speech.

13 221. Banning statements related to the fact that a food is low FODMAP is inherently  
14 content based.

15 222. The Ban results in the suppression of truthful speech about the sale of lawful  
16 products.

17 223. The Ban prevents Ketan, Gourmend, and other businesses from providing highly  
18 valuable information to consumers.

19 224. The Ban does not satisfy any level of First Amendment scrutiny.

20 225. The Ban does not further any legitimate government interests at all and only causes  
21 harm to the public.

22 226. The Ban facially violates Ketan’s and Gourmend’s right to free speech guaranteed  
23 by the First Amendment to the United States Constitution.



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